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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/032,790	10/24/2001	Daniel A. Keys	2064-181	7203

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EXAMINER	
COUNTS, GARY W	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 09/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/032,790	Applicant(s) KEYS ET AL.	
	Examiner Gary W. Counts	Art Unit 1641	

-- The MAILING DATE of this communication appears on th cover sh et with the correspond nc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 July 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *2-4,10-15 and 18-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 5-9, 16, 17 and 26-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the claims

The amendment filed July 11, 2003 is acknowledged and has been entered.

Remarks

Examiner confirms that claims 10-25 are included in the invention of Group I even though they may have been temporarily withdrawn from consideration due to applicants' response to the requirement for an election of species.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 17 is vague and indefinite because of the use of acronyms: i.e. IL-, Ron, VEGF, GMCSF etc..... Although the terms may have art-recognized meanings, it is unclear if applicant intends to claim the prior art definitions. The terms should be defined in their first instance.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

> applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 5-9, 29 and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by Herron et al (US 6,287,871).

Herron et al disclose a method for detecting the concentration of an analyte of interest. Herron et al disclose that the method can detect multiple analytes. Herron et al disclose conducting a fluorescent assay to determine the concentration of analyte (col 3, -col 4). Herron et al disclose employing a computer system comprising a CCD camera (col. 7, line 56 – col. 8, line 67) to detect light signals. Herron et al disclose a solution with a known minimum analyte concentration is analyzed and a solution with a known maximum concentration is analyzed and that the process is repeated with progressively larger known analyte concentrations. The photodetection means determines corresponding fluorescence intensities. Herron et al disclose that the computer calculates the concentration of the analyte of interest (col 15 – col 16). Herron et al disclose that the photodetectors (CCD) could be simultaneous or sequential (col 14).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herron et al in view of Lehmann et al (US 5,939,281).

Herron et al differ from the instant invention in failing to teach the assay is to determine the concentration of a cytokine.

Lehmann et al disclose specific binding reagents, such as antibodies, for detecting the presence or amount of cytokines in a test sample.

It would have been obvious to one of ordinary skill in the art to use the cytokine specific antibodies taught by Lehmann et al in the method of Herron et al because Herron et al is generic with respect to the analyte that is to be detected and one would use the appropriate reagent, i.e. antibody to detect the desired analyte, in this case cytokines.

7. Claims 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herron et al in view of Campbell et al (US 4,946,958).

See above for teachings of Herron et al.

Herron et al differ from the instant invention in failing to teach the light signal is a chemiluminescent light signal.

Campbell et al disclose a chemiluminescent label used in analysis, assay or location of proteins, polypeptides and other substances of biological interest (col. 1). Campbell et al disclose that the use of this chemiluminescent label provides a means of improving the sensitivity of measurement of proteins and polypeptides or other substances of biological interest by one to two orders of magnitude by comparison with existing techniques (col. 7).

It would have been obvious to one of ordinary skill in the art to incorporate the use of a chemiluminescent label as taught by Campbell et al into the method of Herron et al because Campbell et al shows that this chemiluminescent label provides a means of improving the sensitivity of measurement of proteins and polypeptides or other substances of biological interest by one to two orders of magnitude by comparison with existing techniques.

8. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Herron et al in view of McMillan et al (Us 6,057,163).

See above for teachings of Herron et al.

Herron et al differ from the instant invention in failing to specifically teach the well is a multi-well microtiter plate.

McMillan et al disclose the use of a microwell plate to detect luminescence or fluorescence in a sample. McMillan et al disclose that the use of the microwell plate provides a quantitation system for detecting the amount of light emitted by a plurality of samples hold and provides for increased throughput (col 2 & 4).

It would have been obvious to one of ordinary skill in the art to incorporate a microwell plate as taught by McMillan et al into the method of Herron et al because McMillan et al disclose that the use of the microwell plate provides a quantitation system for detecting the amount of light emitted by a plurality of samples hold and provides for increased throughput.

Response to Arguments

9. Applicant's arguments filed July 11, 2003 have been fully considered but they are not persuasive.

Applicant argues that in the Herron et al reference that if the concentration of an analyte is below (or above) the dynamic range of the assay, the CCD report will provide an inaccurate report of the true concentration. This is not found persuasive because applicant has not pointed out the location in the reference, which makes this statement. Further, the computer system and method of Herron et al still reads on applicants claimed limitations (i.e. the computer system causes the CCD camera to detect light signal for the analytes to ensure that the re reported presence, absence, activity or concentration of each target analyte is determined using data corresponding to a light signal that is within the know dynamic range of the assay for the target analyte. Further, Herron specifically teaches that a blank reading is obtained from a blank well, a measurement reading is obtained from the measurement well and a high reading is obtained from another well and that the determination of analyte can be achieved by comparing the measurement reading to the other readings.

Applicant further argues that in accordance with the present invention that if the sample contains low levels of analyte, the assay time can be automatically increased and that if the sample contains excess levels of analyte, that assay time can be automatically decreased. Applicant concludes that methods of the present invention permit such automatic adjustments to be made simultaneously with respect to each analyte being assayed. Such limitations are not found in the claims, it is noted that the

features upon which applicant relies (i.e., if the sample contains low levels of analyte, the assay time can be automatically increased and if the sample contains excess levels of analyte, the assay time can be automatically decreased) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicants arguments directed to the obviousness rejections concerning Lehman et al, Campbell et al, and McMillan et al are not found persuasive because the rejection concerning Herron et al (the primary reference) is maintained and therefore, it is the Examiner's position that the combination of the primary reference and the secondary references is proper and maintained.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (703) 305-1444. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gary W. Counts
Examiner
Art Unit 1641
September 16, 2003

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
09/19/03